4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2020-E-1817, FDA-2020-E-1818, and FDA-2020-E-1820]

Determination of Regulatory Review Period for Purposes of Patent Extension; ENHERTU; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA or the Agency) published a notice in the *Federal Register* of November 1, 2021, for the determination of a regulatory review period for purposes of patent extension for the human biological product, ENHERTU. This document corrects that notice by adjusting the applicable regulatory review period for the testing phase and approval phase of the product, ENHERTU.

DATES: All due dates for submission of comments, redetermination requests, and submission of petitions for due diligence as well as the dates used to determine the regulatory review periods for the products noted above remain the same as originally published.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

SUPPLEMENTARY INFORMATION: On November 1, 2021, the Food and Drug Administration (FDA or the Agency) published a notice in the *Federal Register* determining the regulatory review period for the human biological product ENHERTU. This correction to the notice adjusts the applicable regulatory review period of the product with the number of days occurring during the testing phase and the approval phase of the product ENHERTU.

Correction

In the *Federal Register* of November 1, 2021 (86 FR 60252), in FR Doc. 2021-23725, appearing on page 60253, in the third column, in section II., "Determination of Regulatory Review Period," in the first two sentences, the following correction is made:

FDA has determined that the applicable regulatory review period for ENHERTU is 1,395 days. Of this time, 114 days occurred during the testing phase of the regulatory review period, while 1,281 days occurred during the approval phase.

Dated: January 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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